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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,623	03/10/2004	Edward I. Wulfman	89000.3013NP	6167
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EXAMINER				
WEBB, SARAH K				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/798,623

Applicant(s)

WULFMAN ET AL.

Examiner

SARAH WEBB

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 10, 17, 19, 20 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 10, 17, 19, 20 and 22-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 19 and 20 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 28 recites the limitation "the operating head" in line 1. There is insufficient antecedent basis for this limitation in the claim, as claims 19 and 20 recite "the working head."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2-5, 10, 17, 19, 20, 22-24, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,080,170 (Nash et al.) in view of US Patent No. 5,217,474 (Zacca et al.).

Nash discloses an aspiration catheter that includes all the claimed components and is capable of providing a "liquid seal assembly." As shown in Figure 9A, a housing (400 shown in phantom lines) encloses a drive system (322) for a rotatable torque tube, a proximal end of a catheter (24), a proximal end of a stationary liner (22'), an aspiration port (88), and an infusion port (86). Figure 13 shows greater detail of the attachment of the torque tube (308 and 336) to a drive system (turbine 338) within the housing and a sealing site (326) at the proximal end of the stationary liner (34) within the housing. The infusion port (86) is in communication with the flood space between the torque tube (336/308) and liner (34). Although not specifically stated, the Nash apparatus performs the function of preventing air or other fluids from contacting moveable catheter components in the proximal area of the torque tube.

Figures 10 and 11 show the distal end of the catheter (24) and an atherectomy device (22') disposed within its lumen. As shown in greater detail in Figure 12, the atherectomy device (22') includes a liner (34) surrounding a rotatable torque tube (coiled shaft 308) to define a "liquid flood space" between the two tubular components through which fluid is infused. A working head or cutting head (32") is connected to the distal end of the torque tube (308). The liner (34) terminates proximally to the cutting head (32") at an intersect area (near 304) that allows fluid to exit the flood space to a location proximal to the distal end of the rotatable torque tube (indicated by arrows transverse to longitudinal axis)(column 21, lines 1-20). Fluids are aspirated through the aspiration lumen that is defined between the outer catheter (24) and the atherectomy

catheter (22'), as indicated by arrows (A2) in Figures 10 and 11 (column 16, lines 35-44).

Nash fails to configure the liner (34) to terminate proximal to the distal end of the torque tube (308). Zacca discloses another atherectomy assembly that includes rotatable torque tube (8), a cutting head (16) at its distal end, and a drive assembly (1) at the proximal end. Similar to Nash, a liner (14) surrounds the torque tube (8) and forms a liquid flood space (34) between the two components into which cooling or contrast fluids may flow from infusion port (3)(column 6, lines 40-46). As best shown in Figure 2, Zacca teaches that it is known to form the liner (14) so that it terminates proximally of distal end of torque tube (8). It would have been obvious to one of ordinary skill in the art to modify the liner of the Nash device to terminate proximally of the distal end of the torque tube, as taught by Zacca, as this modification merely involves the combination of known elements according to known methods to obtain the predictable result of a rotatable torque tube with an outer liner.

The language *"a catheter...extending distally to enclose the torque tube and the liner"* in lines 11-12 of claim 19 and section (c) of claim 20 is a recitation of the relative position of two moveable components. Since the outer catheter (24) of the modified Nash apparatus is capable of being moved to a position where its distal end extends beyond the distal end modified liner (34) at an intersect area, it meets the claim requirements.

Regarding claim 3, Nash describes a helical torque tube (308) that meets the requirement of “coiled drive shaft” and mentions gaps in between the coils (column 23, lines 39-50).

Regarding claim 4, Nash discloses a guide wire (124) used with the system and a guide wire lumen shown passing through the torque tube in Figure 12.

Regarding claim 5, the aspiration port (88) serves as a suction port for removing fluid from the aspiration lumen. The recitation of specific working pressures along the length of the device is not given full patentable weight, as it is a recitation of the intended use of the device. The infusion and aspiration pressures are capable of being adjusted as desired to create a lower pressure in the flood space (column 10) so Nash meets this claim.

Regarding claim 10, the device includes additional ports (such as connection of shaft 336 with bearing 350; ports 24A and B in Figures 10 and 11; port 360 in Figure 13) that are capable of functioning as “overflow ports.”

Regarding claims 22 and 23, Nash discloses that the liner (34) has an outside diameter of 1.5mm (0.059 inch) (column 8, line 5) but is silent with respect to its inside diameter and length. It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the liner to have an inner diameter of about 0.03 inch to 0.04 inch and a length of about 6 inches, as a mere change in size of a component is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Regarding claim 24, Nash discloses that the liner (34) is made of plastic (column 8, line 3), which is considered to meet the requirements of thin, tough, flexible, and polymer-based tubing.

Regarding claim 26, Nash discloses that the torque tube can be axially translated by moving handle (416) (column 25, lines 27-42).

Regarding claim 27: Although Nash is silent with respect to the selection of the length and diameter of the liner for the purpose of reducing flow rate and requirement for precise diametrical tolerances, it would have been obvious to optimize the relative dimensions of the liner since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nash in view of Zacca et al. and further in view of US Patent No. 6,258,052 (Milo).

Nash discloses that the liner (34) is plastic and discloses the use of anti-friction sleeves over components of the system (column 13, line 43), but Nash and Zacca fail to specify that the liner comprises polyimide tubing with a lubricious coating. Milo teaches that forming a liner over a coiled shaft from a polyimide tube increases pushability and column strength (col. 2, ln. 61 - col. 3, ln. 2). It would have been obvious to one of ordinary skill to form the modified Nash liner from a polyimide material with a lubricious coating, as it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Webb whose telephone number is (571)272-5749. The examiner can normally be reached on Monday through Friday from 9:00 AM-5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Tom Hughes, at (571) 272-4357***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. W./
Examiner, Art Unit 3731

/Elizabeth Houston/
Primary Examiner, Art Unit 3731